

# Chief Pharmaceutical Inspectorate

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## Voivodship Pharmaceutical Inspector

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- manages the voivodship pharmaceutical inspection which is a part of the integrated voivodship administration. In this case, the public administration authority is the governor who carries out tasks related to Pharmaceutical Inspection with the assistance of the voivodship pharmaceutical inspector, who issues administrative decisions on behalf of the governor,
- manages the voivodship pharmaceutical inspectorate: fulfils tasks and competences of Pharmaceutical Inspection specified in the act of Pharmaceutical Law and other regulations,
- is the first instance body in cases related to the fulfilment of tasks and competences of the Pharmaceutical Inspection,
- is appointed and dismissed by the governor at a request of the Chief Pharmaceutical Inspector.

### **The most important tasks** of the Voivodship Pharmaceutical Inspector

- Issuing decisions with regard to:
- granting or refusing to grant, amending or withdrawing an authorisation to run a pharmacy, or declaring that such authorisation has expired,
- granting or refusing to grant, amending or withdrawing an authorisation to run a pharmacy outlet, or declaring that such authorisation has expired,
- withdrawing authorisations to run a pharmacy,
- withdrawing authorisations to run a pharmacy outlet,
- if it is found that the requirements for storage of and trade in medicinal products and medical devices are not met, removing the found deficiencies within a specified period of time,
- suspending the activity of a pharmacy, a pharmacy outlet or another establishment trading in medicinal products or medical devices,
- withdrawing from the market the specific batch of a medicinal product or medical device within its area, if it has been established that a medicinal product or a medical device does not meet the quality standards established for it,
- marketing of medicinal product only within the authority's area, if it is found that it does not meet the specified quality standards,
- marketing a medicinal product located only within the authority's area, if it meets the specified quality standards,
- releasing healthcare centres from the obligation to run a hospital pharmacy,
- releasing pharmacies from the obligation to sell intoxicants from group I-N and psychotropic substances from group II-P,
- establishing whether an entrepreneur applying for an authorisation to manufacture, process or alternate

intoxicants, psychotropic substances or precursors of category 1 ensured the appropriate manufacturing and trade conditions to protect intoxicants, psychotropic substances or precursors of category 1 against unauthorized use or use for purposes other than those specified in the issued authorisation (Article 35 sec. 6),

- establishing whether an entrepreneur applying for an authorisation for wholesale trade in intoxicants, psychotropic substances or precursors of category 1 ensures trade conditions that prevent unauthorised use of intoxicants, psychotropic substances or precursors listed in the authorisation or use for purposes other than those specified in the authorisation (Article 40 sec 5),
- issuing permissions for possession for medical purposes of preparations containing intoxicants from groups I-N, II-N and III-N and psychotropic substances II-P, III-P and IV-P, permissions to possess preparations used in a clinical trial, by healthcare centres without pharmacies, animal healthcare centres, doctors running an individual medical practice,
- supervises the manufacturing, processing, alteration, storage, trade in and disposal of intoxicants, psychotropic substances and precursors by controlling whether the obligations resulting from Regulation 273/2004, Regulation 111/2005 and provisions of the Act are followed, except entrepreneurs referred to in Article 35 sec. 1 who, in this respect, are supervised by the Main Pharmaceutical Inspector through GMP Inspectors,
- issues authorisations for use of intoxicants, psychotropic substances or precursors of category 1, excluding groups I-P and IV-N, to scientific units for the purpose of scientific research.